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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,342	02/12/2004	Frederic Nefel	B0884.70074US01	4933
7590 Lawrence Green Wolf, Greenfield & Sacks, P.C. 600 Atlantic Avenue Boston, MA 02210			EXAMINER GRAY, PHILLIP A	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 01/29/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/777,342

Applicant(s)

NEFTEL, FREDERIC

Examiner

Phillip Gray

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-4, 6, 10-13 and 25-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-4, 6, 10-13 and 25-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other. \_\_\_\_\_

## DETAILED ACTION

This office action is in response to applicant's communication of 10/30/2007. Currently amended and newly added claims 2-4, 6, 10-13, 25-38 are pending and stand rejected below.

### ***Response to Arguments***

Applicant's arguments filed 10/30/2007 have been fully considered but they are not persuasive. Applicant's argue that the step of "closing the regulation system and the first occlusion system in such a manner that part of said positive pressure is maintained in the intermediate segment, while the pressure in the downstream segment is not maintained at such positive pressure" is not disclosed in Uber. It is examiners position that Uber discloses this in many of the numerous embodiments and systems of Uber. It is examiners position that that when considering the switch 27 to be the first occlusions system the above limitation is satisfied and disclosed, but even arguendo it would also be disclosed if in the alternate backflow prevention systems (and in element 66 as the occlusion system for example see figures 5a-5b). Examiner is reading "*in such a manner that part of said positive pressure is maintained in the intermediate segment, while the pressure in the downstream segment is not maintained at such positive pressure*" as a functional recitation and not a positive limitation but only requires the ability to so perform. Examiner is of the position that Uber does disclose the step of "closing the regulation system and the first occlusion system" and that this closing step does perform or causes "in such a manner that part of said positive pressure is

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maintained in the intermediate segment, while the pressure in the downstream segment is not maintained at such positive pressure”.

### ***Claim Objections***

Claim 26, and 34-38 is objected to because of the following informalities: It is indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim limitation “...a predetermined maximum pressure of the downstream segment in the absence of injection...” is unclear and not descriptive. Examiner is unable to ascertain what is meant by “predetermined maximum pressure”. How is this pressure predetermined? Is this maximum pressure when there is fluid in the device, or when there is no fluid in the device? How or what would be a minimum pressure? What are “bars” and are they units of measurement for the predetermined maximum pressure (examiner is assuming that applicant means “Bar” as in a unit of pressure, equal to  $10^5$  pascal) If so how does this predetermined maximum pressure relate to the opening pressure with the natural occurring barometric pressure? Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 25, 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Uber III (U.S. Patent Number 5,843,037, hereafter "Uber"). Uber discloses a multipatient fluid dispensing system and method of injecting liquid under pressure to a patient (see Uber column 1 generally). Uber discloses a method for injecting that comprises the steps of 1.) **providing liquid under pressure to a patent**, via a set of tubing with an occlusion system and an upstream regulation system, and 2.) **when the injection is to be stopped closing the regulation system** and 3.) **closing the first occlusion system**, and a pressurizing system (such as pump 12). Uber discloses these steps of providing liquid (described in column 2), and closing the regulation system and later the occlusion system disclosed in column 3). It is evident that Uber would disclose providing the liquid and then stopping the liquid by closing the regulation system and the occlusion system. For instance (in figure 1) after supplying the fluid, the valve/pump regulation system elements (12, 20, 21 for one example) would be shut off by electrical control system, and then the occlusion system would be shut off (such as rotary valve 27), as described in paragraphs at column 3. The claim limitations of the intermediate segment (Uber element 26 for example) having an intermediate pressure greater than the downstream segment (36 for example) would be evident in operation of the system. Pressurizing system/Pump 12 would provide a pressure for the system that would be greatest at the upstream end (near 10) and would decrease as the liquid flowed through the system and would least at the end (near patent end 36). This pressure difference would be evident do to the fact that the liquid flows to the patient and not upstream into the reservoir, besides the overall nature of fluid dynamics.

Further the intermediate segment would have a contained intermediate pressure (in supply conduit 26 since oneway valve 25 and rotary valve 27 would seal this segment and maintain a specific intermediate pressure) that would be greater than the downstream end (36) and hence fluid would flow to the end of lower pressure (ie the downstream end). The Uber systems pressure difference between the intermediate pressure and the downstream pressure would prevent the upstream flow of liquid even after the injection has stopped (either by stopping the regulation system, occlusion system or both sequentially or simultaneously). It is examiner's position that Uber discloses all the steps of the method (1. providing liquid, 2. closing the regulation system, 3. closing the occlusion system) and these steps are carried out on a structural apparatus similar to the claimed structural apparatus (tubes with regulation system and occlusion system) and that the intermediate/downstream pressure differential would exist and be present in the system as carried out by the Uber method disclosed.

It is examiner's position that the prior art of record does satisfy and anticipate the claims as amended. The claims as written do not preclude the mechanical regulation of the system as taught in the prior art of record, from anticipating them, and capable of their claimed operation. In operation of the prior art methods and systems, the positive pressure upstream would cause the flow of liquid out to the downstream end of lowest pressure after passing through an intermediate section of intermediate pressure. Closing of regulation systems and occlusion systems would not instantly cause these intermediate pressures to not exist.

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The prior art of record anticipates the pending claims as written because all claim limitations are met and the interpretation of the prior art satisfies all functional, structural, operational and spatial, claim limitations.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-4, 6, 10-13, and 27-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uber in view of Lichtenstein (U.S. Patent Number 4,464,172)

Lichtenstein discloses a computer controlled medical care system for use in the treatment and diagnosis of patients, which provides for either automatic or manual control of a wide variety of medical procedures. Lichtenstein discloses a system of

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tubing and valves for infusion to a patient, which contains a wide variety of sensors. The system may include one or more sensors for determining pressure and rate of fluid flow within ducts and chambers in the module. Also included may be sensors for invasive or noninvasive determination of intravascular pressures within a patient connected with a module and arrangements for gravity flow or pumped flow of fluid between a module and a patient or within the module. The Lichtenstein includes an intermediate segment of tubing with one way valves and various pumps that are monitored and controlled to regulate the pressure and fluid flow to a patient and alarming in response to various outputs. (see paragraphs beginning at column 7 line 53, to column 12 line 54).

Uber discloses the claimed invention except for the leakage monitoring and alarming and one-way valve. Lichenstein teaches that it is known to use leakage monitoring and alarming with a one-way valves as set forth in paragraphs at column 7 line 53, to column 12 line 54 to provide a controlled and efficient means for fluid transfer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Uber with the leakage monitoring and alarming with one-way valve as taught by Lichenstein, since such a modification would provide the method with leakage monitoring and alarming with a one-way valve for providing a controlled and efficient means for fluid transfer.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Teirstein (U.S. Patent Number 5,533,978)



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Hellman et al. (U.S. Patent Number 5,569,181)

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571) 272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
PAG

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

